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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,300	09/13/2001	Helmut Eckert	0147-0229P	2392

2292 7590 03/22/2005

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,300	ECKERT ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,12 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-9,12 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Eckert *et al*

Priority Date: 13 January 1999

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/2004 has been entered.

2. Claims 1,7-9,12, and 14 are pending and examined on the merits.

Information Disclosure Statement

3. The Information Disclosure Statement filed 12/23/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1,7-9,12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragnhammar *et al* (Int. J. Cancer 1993; 53:751-758 – IDS 12/23/04). The claims are

drawn to a pharmaceutical composition comprising an antibody directed against EP-CAM and at least one adjuvant, wherein the antibody is a murine monoclonal antibody, wherein the variable regions is amino acid sequence SEQ ID Nos.: 1 and 2. The claims are further limited to said antibody is contained in a dosage range of 0.01-4mg. The claims are also drawn to a method of treating cancer comprising the administration to a patient in need thereof the said pharmaceutical composition, wherein the composition is administered by subcutaneous, intradermal, or intramuscular injection, wherein the antibody is administered in a dosage range of 0.01-4 mg or specifically 0.5mg.

It is noted for the record that in a communication filed 12/23/2004 that the applicant indicates *"the monoclonal antibody HE2 is identical to the monoclonal antibody 17-1A described in the Ragnhammer publication submitted."*

Ragnhammar *et al* teach a pharmaceutical composition comprising a monoclonal murine antibody termed 17-1A in a dosage range of 0.01-4 mg (specifically, it is taught that the dose is 1.0 mg – see page 751). The art also defines 17-1A antigen as EP-CAM (as evidenced by Balzar et al J. Mol Med 1999;77:699-712 – previously cited). Moreover, the specification defines an "adjuvant" as a biological agents of which includes GM-CSF (see specification page 9), the GM-CSF used by Ragnhammar *et al* therefore falls within the scope of a pharmaceutical adjuvant as claimed. In addition, Ragnhammar *et al* also teach a method of treating cancer comprising the intradermal administration of the said 17-1A pharmaceutical composition in the dose range of 0.01-4 mg. It is also disclosed that the said antibody can be administered in the dosage of 0.5 mg (Ragnhammar *et al* teach that a dose of 2-4 mg of the 17-1A antibody is

administered daily at 4hr infusion times, therefore there are 6 infusions per day at a dosage of 0.5 mg 17-1A).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/17/05

Christopher Yaen
Art Unit 1642
March 10, 2005